

## II. REMARKS

The Office Action dated June 23, 2009, has been received and carefully noted. The following amendments and remarks are submitted as a full and complete response thereto.

Claims 1-3 and 5-42 are pending. Claims 3, 10-18, and 21-42 are withdrawn from consideration.

By this Amendment, claim 1 is amended. Support for the amendment can be found in the claims and specification as originally filed. For example, claim has been amended to recite that the dibasic calcium phosphate, anhydrous has a "Ca to P ratio of 1." Applicants submit that support for this amendment can be found in the specification at least on page 10, line 14 (which refers to Fujicalcin™). Applicants submit that one of ordinary skill in the art would understand that Fujicalcin™ refers to  $\text{CaHPO}_4$ , which has a Ca/P ratio of 1, as evident in the Fujicalcin™ product information sheet which was previously submitted. Applicants submit that no new matter has been added and respectfully request reconsideration and withdrawal of the pending rejection.

Claims 1, 2, 5-9, 19 and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tsuru (EP 0 376 331, hereinafter "Tsuru") in view of Holmberg (WO 01/66088, hereinafter "Holmberg").

Presently amended claim 1 is directed to a "solid drug delivery composition comprising one or more NO-donating Non Steroidal Antiinflammatory Compound (s) (NO-donating NSAID(s)) absorbed into porous particles, wherein the porous particles comprise a member selected from the group consisting of: dibasic calcium

phosphate, anhydrous, having a Ca to P ratio of 1; microcrystalline cellulose; pregelatinised starch; calcium silicate; magnesium aluminometasilicate; and mixtures thereof.” Claims 2, 5-9, 19, and 20 depend from independent claim 1.

Applicants submit that Tsuru does not teach or suggest the presently claimed invention. For example, Application submit that Tsuru discloses slow release drug delivery granules comprising porous granules of a calcium phosphate compound having a Ca to P (Ca/P ratio) of 1.3 to 1.8 (page 2, line 49). As noted previously, Applicants submit that the calcium phosphate disclosed in Tsuru refers to salts containing calcium ions ( $\text{Ca}^{2+}$ ), together with an orthophosphate ion ( $\text{PO}_4^{3-}$ ) or pyrophosphates ( $\text{P}_2\text{O}_7^{4-}$ ), and the atomic ratio Ca/P is always greater than 1. For example, Applicants submit that hydroxyapatite (disclosed in Example 1 of Tsuru et al.) has the formula  $\text{Ca}_5(\text{PO}_4)_3(\text{OH})$  and an atomic ratio Ca/P of 1.67, and tricalcium phosphate (disclosed in Example 3 of Tsuru et al.) has the formula  $(\text{Ca})_3(\text{PO}_4)_2$  and an atomic ratio Ca/P of 1.5.

Further, Applicants submit that Tsuru et al. also fails to teach or suggest the other porous particles of claim 1, in particular microcrystalline cellulose, pregelatinised starch, calcium silicate, and magnesium aluminometasilicate, or mixtures thereof.

Applicants submit that Holmberg et al. does not fulfill the deficiencies of Tsuru et al. For example, Applicants submit that Holmberg et al. discloses a pharmaceutical composition in the form of an emulsion pre-concentrate, comprising one or more NO-releasing NSAIDs, one or more surfactants, and optionally an oil or semi-solid fat (page 4, lines 6-12). Holmberg et al. discloses NO-releasing naproxen

(formula (Ia), page 8). However, there is no prima facie case of obviousness with the combination of Holmberg et al. with Tsuru et al.

For at least the above reasons, Applicants submit that the presently claimed invention is patentable over Tsuru et al. and Holmberg et al. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 2, 5-9, 19 and 20 under 35 U.S.C. § 103(a).

## II. CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this response is not timely filed, the Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other additional fees which may be required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 026220-00054.

Respectfully submitted,



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